

## Participant Information and Consent Form - Carers

<b>Title</b>	Managing Cancer and Living Meaningfully (CALM) in people with non-small cell lung cancer treated with novel therapies: A pilot study
<b>Principal Investigator</b>	Dr Fiona Lynch
<b>Protocol Version</b>	V2 11 <sup>th</sup> November 2022
<b>Ethics Approval Number</b>	21/245

### 1 Introduction

You are invited to take part in this project because you are a support person for someone with lung cancer who has received a psychology therapy called Managing Cancer and Living Meaningfully (CALM) as part of the Peter Mac CALM in Lung Cancer pilot study. This study aims to assess the acceptability and feasibility of CALM with people with advanced lung cancer who have received novel therapies (immunotherapies or targeted therapies) at Peter MacCallum Cancer Centre.

This form explains the project and what you will do if you decide to take part. Please read this information carefully. Please ask questions about anything you do not understand or want to know.

Your participation in this project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw. Your decision to take part or not to take part in this project, or to take part and then withdraw, will not affect your relationship with the project staff.

There are no costs associated with participating in this research project, nor will you be paid.

### 2 What is the purpose of this project?

The purpose of this research is to understand the usefulness of the CALM therapy for people with advanced lung cancer who have been treated with novel therapies. CALM has been developed for people with advanced cancer but has not yet been assessed for people treated with novel therapies. We aim to get feedback from patients and carers about their experience of the CALM therapy.

This project is led by Dr Fiona Lynch, Clinical Psychologist at Peter Mac. The project is funded by a Peter Mac Cancer Foundation Grant.

### 3 What will I need to do if I am involved in this project?

If you choose to take part in this project, you will complete a once-off interview with the person with lung cancer about your experience of the CALM therapy. This interview will be completed over the phone, over telehealth (video-call) or in person, depending on your preference. The interview will be conducted by a member of the research team. At the start of the interview you will be asked to verbally consent to the interview and to your information being temporarily stored and analysed for the purposes of this research project. The interview will last for approximately 30-45 minutes and be conducted by a member of the research team. This interview will be audio recorded and transcribed for analysis.

You will also be asked a few questions about yourself so we can understand who is taking part.

Should you wish to receive the overall results of this project you should inform the project team at the time of providing consent. We will send you these results at the end of the project.

### 4 What are the possible risks or disadvantages of taking part?

There are no anticipated risks associated with this project.

5      **What if I withdraw from this project?**

If you do consent to participate, you may withdraw at any time up until the completion of the project or until your interview has been analysed, whichever comes first. If you decide to withdraw from the project, please notify a member of the research team.

You should be aware that data collected up to the time you withdraw will form part of the overall project results. If you do not want your data to be included, you must tell the project team member when you withdraw from the project. After completion of the project, your data will be included in the overall results and you will no longer be able to withdraw your data.

6      **What will happen to information about me?**

By verbally consenting, you consent to the project team collecting and using personal information about you for the evaluation of this project as described. The information you supply will be stored in password protected computer files accessible only to the project team. The information will be kept in a de-identified format to protect your privacy, that is, formatted in a way that it will not be possible for you to be identified.

This de-identified information will be stored for a period of seven (7) years and then will be confidentially destroyed.

The results of this project may be published in scientific journals or presented at seminars and conferences, but it will be done in a way that cannot identify you. Some journals may keep the overall de-identified data for an indefinite period.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the project team. You have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

7      **Who has reviewed the project?**

All research in Australia involving people is reviewed by an independent group of people that form a Human Research Ethics Committee (HREC). The ethical aspects of this project have been approved by the HREC of the Peter MacCallum Cancer Centre.

This project will be carried out in accordance with the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*. This statement has been developed to protect the interests of people who agree to participate in research conducted with or about people.

8      **Further information and who to contact**

If you want any further information about this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the Project Lead Fiona Lynch on 8559 8236 or any of the following people:

Project contact person	Peter Mac complaints person	Peter Mac Ethics Committee
Fiona Lynch	Position Consumer Liaison	Peter Mac Ethics Coordinator
Telephone: (03) 8559 8236	Telephone: (03) 8559 7517	Telephone: (03) 8559 7540
Email: <a href="mailto:fiona.lynch@petermac.org">fiona.lynch@petermac.org</a>	Email: <a href="mailto:consumerliaison@petermac.org">consumerliaison@petermac.org</a>	Email: <a href="mailto:ethics@petermac.org">ethics@petermac.org</a>

**Consent Form**

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<b>Project and Ethics Approval Number</b>	21/245L
<b>Project Sponsor</b>	Peter MacCallum Cancer Centre
<b>Principal Investigator</b>	Dr Fiona Lynch

**Declaration by participant**

- I have read the Participant Information and Consent Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the project.
- I have had an opportunity to ask questions about the project and what is required of me, and I am satisfied with the answers I have received.
- I freely agree to participate in this project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- I understand that I will be given a copy of this document to keep.

☐ Participant clearly states their agreement to participate

**Declaration by Researcher<sup>†</sup>**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher <sup>†</sup> (please print) _____	
Signature _____	Date _____

<sup>†</sup> An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.